REMARKS

Claims 7, 8 and 11 are pending in the present Application. Claims 1-6 and 9-10 have been cancelled, claim 7 have been amended, leaving claims 7, 8 and 11 for consideration upon entry of the present Amendment.

Claim 7 has been amended to better define the invention. Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Priority

In this Office Action, the Examiner noted that certified copies of foreign applications have not been filed a required by 35 U.S.C.119(b). (Office Action dated 9/12/2008, page 3) In the previous response, we noted to the Examiner that this application was a 371 national stage entry of a PCT claiming priority to Korean Patent Application No. 10-2004-0011327 and Korean Patent Application No. 10-2005-0013395 and that copies of these documents should have been provided to the USPTO by the International Bureau. (Amendment and Response filed 6/13/2008) Attached herewith is a copy of PCT/IB/304 to document that certified copies of the two priority applications were indeed received by the International Bureau. Therefore, Applicants believe that the USPTO should have received a certified copy of Korean Patent Application No. 10-2004-0011327 and Korean Patent Application No. 10-2005-0013395 via the International Bureau, thus meeting the requirements 35 U.S.C.119(b).

In this Office Action, the Examiner noted that a translation of the foreign document has not been received. (Office Action dated 9/12/2008, page 3) Applicants respectfully submit that an English language translation of a non-English language foreign application is not required except: (A) when the application is involved in an interference, (B) when necessary to overcome the date of a reference relied upon by the examiner, or (C) when specifically required by the examiner. (37 CFR § 1.55(a)(4)) Thus, Applicants believe that an English Translation (certified copy) is not required at this time.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 7, 8 and 11 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement because the claims contain subject matter that was not

described in the specification in such a way as to reasonably convey to a person skilled in the pertaining art to make and/or use the invention. (Office Action dated 9/12/2008, page 3) Applicants respectfully traverse this rejection.

"To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 219 (CCPA 1976).

Applicants contend that claims 7-8 meet the enablement requirement. The specification discloses the nucleotide sequence of SEQ ID NO 5 (see sequence listing), and teaches, as evidenced by an association study, that the alleles of the SNP at position 101 of the sequence are associated with an increased risk of developing colorectal cancer in a Korean human having the appropriate base at the SNP site (see Table 1). Applicants note that for the SNP at position 101 of SEQ ID NO 5 the chi-square p-value of 4.62×10^{-3} is related to comparing genotype frequency in the case vs. control groups (page 7, lines 1-10); the odds ratio of 1.52 represents the ratio of the probability of risk allele in the case group to the probability of the risk allele in the normal group (page 7, lines 15-17); and the confidence interval of 1.182 and 1.961 are related to the association of the risk allele with disease (page 7, lines 17-20). Applicants respectfully submit that when the p-value ≤ 0.05 it is considered that the genotype of the case group is different from that of the normal group. Thus, a chi-square p-value of 4.62×10^{-3} clearly indicates that there are significant differences between expected values and measured values in allelic frequency at the polymorphic site at position 101 of SEQ ID NO: 5, and that an odds ratio falling within the range of 1.30 to 2.06 shows that the polymorphic marker is associated with colorectal cancer (page 8, lines 1-7). Further, Applicants submit that Table 1 clearly demonstrates that by determining the base at the polymorphic site is a G compared with determining the base is a T indicates the Korean human is at an increased risk of developing colorectal cancer, regardless of whether the Korean human has a GT or GG genotype.

In summary, Applicants believe that Table 1 demonstrates that the SNP at position 101 of SEQ ID NO 5 is associated with colorectal cancer and that by determining the base at position 101 of SEQ ID NO 5 is guanine (G) indicates an increased risk of developing colorectal cancer compared to determining the base is thymine (T). For this reason at least, Applicants believe that

the specification fully enables one of skill in the art to make and use the claimed invention without undue experimentation. Applicants request a withdrawal of the rejection and allowance of the claims.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 7, 8 and 11 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action dated 9/12//2008, page 8) In particular, the Examiner stated that the preamble of claims 7, 8 and 11 requires a method of determining any risk of developing colorectal cancer, yet the final process step is limited to an increased risk. The Examiner further stated that it is unclear whether the method is directed to any risk as suggested by the preamble or only to increased risk as suggested by the final step. (Office Action dated 9/12//2008, page 8) Applicants respectfully traverse this rejection.

As suggested by the Examiner, claim 7 has been amended to recite "determining an increased risk of developing colorectal cancer in a Korean human." Applicants believe that amended claim 1 meets the requirements of 35 U.S.C. § 112, second paragraph. Applicants respectfully request a withdrawal of the rejection of claims 7, 8 and 11 under 35 U.S.C. § 112, second paragraph, and an allowance of the claims.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance are requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

CANTOR COLBURN LLP

By__/Ian J.S. Lodovice/_____
Ian J.S. Lodovice
Registration No. 59,749

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CANTOR COLBURN LLP
20 Church Street, 22nd Floor
Hartford, CT 06103
Telephone (860) 286-2929
Facsimile (860) 286-0115
Customer No.: 23413